CHAPTER 1

1.0 INTRODUCTION

1.1 PURPOSE AND SCOPE

This handbook, *Risk Assessment Handbook: Volume I - Human Health Evaluation*, provides technical guidance to the U.S. Army Corps of Engineers (USACE) risk assessors and risk assessment support personnel for planning, evaluating, and conducting Human Health Risk Assessments (HHRAs) in a phased hazardous, toxic, and radioactive waste (HTRW) response action. The handbook, a compendium to the *Risk Assessment Handbook: Volume II - Environmental Evaluation* (Engineer Manual (EM) 200-1-4), encourages the use of "good science" within the framework of existing U.S. Environmental Protection Agency (USEPA) risk assessment guidelines.

Reference and overview resources:
- Required and Related References (Appendix A)
- Abbreviations and Acronyms (Appendix B)

Risk characterization is a similar process for both human health and Ecological Risk Assessments (ERAs). The fundamental paradigm for human health risk characterization has four phases: (1) hazard identification, (2) dose-response assessment, (3) exposure assessment, and (4) risk characterization. Similarly, the fundamental framework for ecological risk characterization includes four phases: (1) problem formulation, (2) ecological effects characterization, (3) exposure characterization, and (4) risk characterization.

This handbook encourages the concurrent assessment of human and ecological risks so that data collection activities are coordinated and risk managers are provided risk characterization results in a timely manner. Risk characterization results for human and ecological receptors should be reasonable and communicated to the risk managers in a clear and unbiased manner to facilitate the making of balanced and informed risk management decisions.

1.1.1 Objectives. The overall objective of this handbook is to allow the users to be familiar with the risk assessment process so that quality data will be collected and used in preparing a site-specific risk assessment. Specifically, the objectives are:

- To provide guidance for all risk assessments completed under contract with USACE or those for which USACE provides technical oversight (including active Installation Restoration Program [IRP] and Formerly Used Defense Sites [FUDS] and other Federal agencies/facility sites), in compliance with Federal environmental laws and regulations.

- To allow users to be familiar with the application of the data quality design process with respect to conducting risk assessments, so that data collected will support risk assessment conclusions.

- To highlight those decision criteria specific to each phase of HTRW project execution that support risk management decisions.

- To provide minimum requirements for evaluating contractor-prepared risk assessments, assuring that the assessment will adequately support site decisions of an HTRW response action.

- To acknowledge areas of uncertainties where "good science," based on professional judgement and sound scientific principles, is used to determine the need for removal actions or interim measures, further investigation, further action, or no further action (NFA) needed (site closeout).

- To refine understanding of EPA's concepts and application of risk assessment guidelines for site assessment and remediation, especially to support the USACE HTRW program goals.

1.1.2 Scope. This guidance document is not intended to be a "how to" manual which prescribes step-by-step procedures or instructions for preparing an HHRA. Rather, it presents recommendations for scoping, managing, evaluating, and communicating to risk managers and other stakeholders the potential risks posed by hazardous Chemicals Of Concern (COCs) at Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) sites, Resource

Conservation and Recovery Act (RCRA) sites, and other sites managed under the HTRW program. This handbook provides concepts for performing a risk assessment consistent with "good science" and accepted regulatory procedures. The following areas are not covered in this handbook:

- Biological hazards - microbes (natural or genetically engineered) and other biological agents.
- Radioactive hazards - radioactive wastes, radiation generating devices, and radioactively contaminated materials.
- Lead-based paint and asbestos hazards.
- Physical hazards - building demolition/debris removal.
- Study elements and regulatory requirements of a Natural Resource Damage Assessment.

1.1.3 Intended Audience and Use. This document is prepared primarily for use by USACE personnel who are responsible for scoping, directing, and reviewing HHRAs performed for HTRW response action sites. The guidelines provided by this document are consistent with and should be considered in addition to existing EPA guidance contained in the *Risk Assessment Guidance for Superfund (RAGS), Volume I, Part A* (USEPA, 1989j), *Part B* (USEPA, 1991d), *Part C* (USEPA, 1991e), and *Part D* (USEPA, 1998a), and *Data Usability for Risk Assessments* (USEPA, 1992h). The EM entitled *Technical Project Planning (TPP) Process (EM 200-1-2)* (USACE) should be reviewed, particularly for understanding the process described in Chapter 2 of this handbook on how to determine data quality objectives (DQOs) to support a risk assessment.

The data collection, assessment, characterization of risk and uncertainty, and the risk management decision-making (RMDM) aspects presented in this handbook are intended to satisfy RCRA and CERCLA regulatory requirements. The assessment of human health risks under these two functionally equivalent programs is essentially the same. If both regulatory programs are applicable at a site or unit, the risk assessment components should be closely coordinated to avoid duplication of effort. Where possible, the technical and risk management approaches should be incorporated as specific language in agreements with EPA or states.

1.1.4 Contents of the Handbook. Chapter 1 presents the purpose, scope, concept, science/policy considerations, and the use of risk assessment in HTRW programs. It provides a description of the USACE HTRW program, quality required for performing a risk assessment, and an understanding of how risk assessments serve management decision needs. Relevant Federal statutes/regulations, agency guidance and directives, and state requirements are highlighted in this chapter.

Chapter 2 presents the major scoping or project planning elements under CERCLA as amended by the Superfund Amendments and Reauthorization Act (SARA) of 1986, and RCRA as amended by the Hazardous and Solid Waste Amendments (HSWA) of 1984. Particular emphasis is placed on the early development of a conceptual site model (CSM) in the data quality design process to identify data needs, optimize data collection efforts, and recommend options for site decisions.

Chapter 3 provides an introduction to the HHRA process as it applies to screening-level assessments. Screening-level HHRAs are typically utilized in the Preliminary Assessment/Site Inspection (PA/SI) or RCRA Facility Assessment (RFA) stage of site investigations.

Chapter 4 is intended to provide the risk assessor with the minimum content expected to be included in a Baseline Risk Assessment (BRA), conducted during the Remedial Investigation (RI) or RCRA Facility Investigation (RFI) phase of investigations. This chapter stresses the importance of properly identifying the Chemicals of Potential Concern (COPCs) and developing a thorough understanding of the dynamics or inter-relationships of multiple pathway exposure models. Appropriate methods for estimating exposure point concentrations are also presented. The importance of objectively and realistically characterizing site hazards or risks is discussed relative to satisfying the regulatory requirements of protectiveness of human health and the environment.

Chapter 5 provides the risk assessor with information to evaluate risk assessments conducted during the Feasibility Study (FS) or Corrective Measures Study

(CMS) and Remedial Design/Remedial Action (RD/RA) or Corrective Measures Implementation (CMI) phases of investigations.

Chapter 6 provides guidance on the risk and uncertainty aspects of RMDM. Both risk and non-risk information are collected and presented for consideration by the manager. This chapter emphasizes balancing the need for protection of human health with other project constraints, including the level of confidence and uncertainty in the risk assessment results. It details approaches for evaluating the need for NFA, removal (or interim corrective measure), and remediation. Additionally, Chapter 6 provides the risk assessment information inputs into the decision criteria and rationale for the selection of remedial alternatives or corrective measures. Chapter 6 concludes that the risk assessor is responsible for presenting key risk information to be used as input into risk management options including documentation of uncertainty and rationale.

1.2 USACE ROLE IN THE HTRW PROGRAM

In the execution of USACE environmental missions, the HTRW program is organized and staffed to respond to assignments for the following national environmental cleanup programs:

- EPA Superfund Program (CERCLA)
- Defense Environmental Restoration Program (DERP):
  - IRP
  - FUDS
  - Department of Defense and State Memorandum of Agreement/Cooperative Agreement Program (DSMOA/CA)
- Base Realignment and Closure (BRAC)
- Environmental Compliance Assessment System (ECAS) (USACE 1992a)
- HTRW environmental restoration support for Civil Works projects and other Federal agencies (Department of Defense [DOD] and non-DOD)

For the purpose and intended use of this risk assessment handbook, the focus is on the DERP and BRAC cleanup programs to address CERCLA- and RCRA-related issues.

1.2.1 DERP. DERP, codified in 10 USC Chapter 160, provides central program management for the cleanup of DOD hazardous waste sites consistent with the provisions of CERCLA. The goals of the program are: (1) the identification, investigation, research, and cleanup of contamination from hazardous substances; (2) correction of other environmental damage which creates an imminent and substantial endangerment to the public health or the environment; and (3) demolition and removal of unsafe buildings and structures.

1.2.2 BRAC. BRAC is an environmental restoration program with the mission to restore or clean up DOD installations in preparation of real property disposal or transfer. The Base Closure Account (BCA) funds the BRAC program. The BCA is authorized under the Defense Authorization Amendments and Base Closure and Realignment Act of 1988 and the Defense Base Closure and Realignment Act of 1990. These funds are used to define the nature and scope of contamination, perform RA, and document the condition of real property by issuance of the Finding of Suitability to Lease (FOSL) (DOD, 1993) and the Finding of Suitability to Transfer (FOST) (DOD, 1994a). The Community Environmental Response Facilitation Act (CERFA) (Public Law 102-426) amends CERCLA Section 120(h) and requires Federal agencies to define "real property" on which no hazardous substances and no petroleum products or their derivatives were stored for 1 year or more, were known to have been released, or were disposed of before the property can be transferred. Transfer of contaminated property is allowed as long as the RA to clean up the site is demonstrated to be effective to EPA.

1.2.3 Others. Other components of the USACE HTRW program include:

- EPA Superfund program support - Through an interagency agreement (IAG) and upon EPA request, USACE acts as the Federal government's contracting officer in conducting "Federal Lead" RD and construction activities. USACE may also provide other technical assistance to EPA in support of response actions.

- DSMOA/CA - DOD reimburses states and territories up to one percent of the costs for technical services for environmental restoration cleanups. USACE is responsible for execution of activities which include establishing, managing, implementing, and monitoring the DSMOA/CA program.

- Non-mission HTRW work for others - Through IAGs, non-DOD Federal agencies utilize the technical expertise and experience in work relating to the RCRA, CERCLA, and underground storage tank (UST) investigation and response actions under the HTRW program for non-DOD Federal agencies.

- Guidance for Civil Works projects - The Civil Works districts may request technical support and guidance from HTRW program elements.

1.2.4 HTRW Program Organization. Army Regulation (AR) 200-1 (USA) and USACE HTRW Management Plan (USACE, 1996a) describe the USACE organizational elements in support of DERP, BRAC, and other programs. Their major responsibilities include, but are not limited to, the following:

- The Assistant Secretary of the Army for Installations, Logistics, and the Environment (ASA [I,L,E]).

- Headquarters, U.S. Army Corps of Engineers (HQUSACE) - The Military Programs Directorate - Environmental Restoration Division (CEMP-R) develops, monitors, coordinates, and proposes program management policies and guidance, and provides funding and manpower requirements to the program customers.

- The Director of Environmental Programs (DEP) within the office of the Assistant Chief of Staff for Installation Management (ACSIM) is responsible for interfacing with Department of the Army (DA) components for policies and funds for IRP/FUDS/BRAC executed by USACE.

- HTRW Center of Expertise (CX) is primarily responsible for maintaining state-of-the-art capability, providing technical assistance to other USACE elements, providing mandatory review of designated HTRW documents, and as requested, providing technical and management support to HQUSACE.

- Ordnance and Explosives (OE) CX is primarily responsible for maintaining state-of-the-art technical capabilities in OE, performing SIs, Engineering Evaluations and Cost Analyses (EE/CAs), and removal design phases of OE projects.

- Divisions are responsible for providing program oversight of all HTRW environmental restoration projects and designating project management assignments for HTRW projects.

- HTRW design districts provide the Division Commander with technical support in the areas of health and safety, chemical and geotechnical data quality management, environmental laws and regulations, risk assessment, contracting and procurement, and technical design and construction oversight.

- Geographic districts are responsible for managing the execution of RAs as well as PAs, removal design, and removal action related to the FUDS program.

1.3 OVERVIEW OF HTRW RESPONSE PROCESS

HTRW response actions involve all phases of a site investigation, design, remediation, and site closeout. The HTRW response action process is phased and performed in accordance with EPA procedures for assessing uncontrolled hazardous waste sites under CERCLA or RCRA. The following sections generally describe the CERCLA and RCRA processes, which are functionally equivalent to one another in objectives and types of site decisions to be made throughout each process.

1.3.1 CERCLA Process. CERCLA, commonly known as "Superfund," establishes a national program for responding to uncontrolled releases of hazardous substances into the environment. The regulation implementing CERCLA is the *National Oil and Hazardous Substances Pollution Contingency Plan* (NCP) (USEPA, 1990c). In general, the CERCLA process consists of the site assessment phase and the remedial phase as described below; however, removal actions (as allowed by the NCP) may be taken at any

time during the CERCLA process. It should be noted that the general framework established under the CERCLA process has been adopted for use in environmental cleanup under other programs, e.g., the cleanup of petroleum, oil, and lubricants (POLs)[1] at FUDS or active installations not listed on the proposed or final National Priorities List (NPL). Therefore, certain CERCLA project phases described below (specifically, the Hazard Ranking System [HRS], NPL, and site deletion), are not applicable to these types of sites.

1.3.1.1 Site Assessment Phase - To Identify Sites for Further Evaluation.

- **Site Discovery** - EPA identifies and lists in the CERCLA Information System (CERCLIS) possible hazardous substance releases to be evaluated under Superfund.

- **PA** - While limited in scope, a PA is performed on sites listed in CERCLIS to distinguish sites which pose little or no threat to humans and the environment and sites that require further investigation or emergency response.

- **SI** - An SI identifies sites which (1) have a high probability of qualifying for the NPL or pose an immediate health or environmental threat that requires a response action, (2) require further investigation to determine the degree of response action required, and/or (3) may be eliminated from further concern.

- **HRS** - At the end of both the PA and SI, EPA applies a scoring system known as the HRS to determine if a site should receive a "no further remedial action planned" recommendation or be listed on the NPL for further action. An HRS can also be used to support other site evaluation activities under CERCLA (see *The Revised Hazard Ranking System*, USEPA, 1992a). Although HRS scoring is the EPA's responsibility, site investigations should be designed in such a way as to assure that adequate data is available for EPA to perform the scoring.

- DOD has developed the *Relative Risk Site Evaluation Primer* (1994b) to rank sites primarily for resource allocation and program management purposes. Although neither a replacement nor alternative for HRS scoring, this model suggests that stakeholders consider evaluation factors (contaminant hazard factor, migration pathway factor, and receptor factor) to categorize sites according to "high," "medium," and "low."[2]

- **NPL** - Sites placed on the NPL (based on an HRS score of 28.5 or greater, state nomination, issuance of a health advisory by the Agency for Toxic Substances and Disease Registry (ATSDR), or other method) are published in the Federal Register and are eligible for Superfund-financed RA. DOD sites on the NPL, although not eligible for Superfund-financed RA, are eligible for Defense Environmental Restoration Account (DERA)-funded response actions.

1.3.1.2 Remedial Phase - To Determine the Degree of Risk Based on Nature and Extent of Contamination and Implement Cleanup Remedies if Warranted.

- **RI** - The RI is a field investigation to characterize the nature and extent of contamination at a site and implement cleanup remedies if warranted. A BRA, which includes both a HHRA and an ERA, is performed as part of the RI. The BRA is a component of the RI/FS report.

- **FS** - Based on data collected during the RI[3], remedial alternatives are developed, screened, and analyzed in detail. After potential alternatives are developed, they are screened against three broad

[1] POLs are not listed as hazardous substances under CERCLA and therefore are not subject to CERCLA response actions. However, unless the state has specific requirements for remediating POL sites, the CERCLA process may be utilized to address the site.

[2] The *Relative Risk Site Evaluation Primer* (DOD 1994b) has replaced the Defense Prioritization Model, which has features comparable to the HRS.

[3] If the BRA contained in the RI indicates that risks are acceptable or insignificant, the FS will not be done and the site will be closed out.

criteria: effectiveness, implementability, and cost. Those alternatives which pass this initial screen will be further evaluated according to EPA's nine criteria[4] and other risk management considerations not included in the criteria (e.g., environmental justice under Executive Order (EO) 12898) before one or more of such remedies is proposed for selection.[5]

- **Proposed Plan/Record of Decision (ROD)** - After the RI/FS process has been completed, a Proposed Plan is made available for public comment. The Proposed Plan identifies the remedies for the site jointly selected by the lead agency and the support agencies, and indicates the rationale for the selection. All final decisions and response to public comments are entered in a legal administrative record, the ROD.

- **RD/RA** - RD is a subactivity in remedial implementation where the selected remedy is clearly defined and/or specified in accordance with engineering criteria in a bid package, enabling implementation of the remedy. RA is a subactivity in remedial response involving actual implementation of the selected remedy.

- **Five Year Review/Site Deletion** - Upon completion of all RAs, CERCLA and the NCP allow for the reclassification or deletion of the site from the NPL. If an RA results in any hazardous substances remaining on site, CERCLA Section 121(c) requires a review of the remedy once every 5 years to assure that: (1) the site is maintained, i.e., the remedy (including any engineering or institutional controls) remains operational and functional; and (2) human health and the environment are protected, i.e., the cleanup standards (based on risk or ARARs) are still protective.

1.3.1.3 Removal Action - To Prevent, Minimize, Stabilize, or Mitigate Threat to Humans and the Environment.

CERCLA Section 104 Removal Actions can take place at anytime during the entire CERCLA process. Unlike RAs, removal actions are not designed to comprehensively address all threats at the site. Removal actions may be emergencies (within hours of site discovery), time-critical (initiated within 6 months), non-time-critical (planning for the removal action takes 6 months or longer), or early actions. EE/CAs, comparable to FSs, are required for removal actions that are deemed non-time-critical.

1.3.2 RCRA Corrective Action Process. RCRA requires corrective action for releases of hazardous waste or hazardous waste constituents from Solid Waste Management Units (SWMUs) at hazardous waste Treatment, Storage and Disposal (TSD) Facilities with a permit and those seeking a RCRA permit or approval of final closure. The owner or operator of a facility seeking a RCRA permit must:

- Institute corrective action as necessary to protect human health and the environment from all releases of hazardous waste, and hazardous constituents from any SWMU at the facility.

- Comply with schedules of compliance for such corrective action.

- Implement corrective actions beyond the facility boundary.

The corrective action process has four main components: an RFA, an RFI, a CMS, and a CMI.

- **RFA** - An RFA is designed to identify SWMUs which are, or are suspected to be, the source of a release to the environment. The RFA begins with a preliminary review of existing information on the facility, which may be followed by a visual site inspection. The RFA will result in one or more of these actions: (1) NFA is required, (2) an RFI is to

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[4] The nine criteria are: (1) overall protection of human health and the environment; compliance with Applicable or Relevant and Appropriate Requirements (ARARs); (3) long-term effectiveness/permanence; (4) short-term effectiveness; (5) reduction of toxicity, mobility, or volume; (6) implementability; (7) cost; (8) state acceptance; and (9) community acceptance.

[5] If the RI shows no unacceptable risk, regulators may agree to eliminate the FS and proceed directly to a no-action proposed plan.

be conducted to further investigate the documented or suspected releases, (3) interim measures are necessary to protect human health or the environment, and (4) referral to other authorities to address problems related to permitted releases.

- **RFI** - An RFI may be required based on the outcome of the RFA. An RFI is accomplished through either a permit schedule of compliance or an enforcement order. The extent of the investigation can vary widely since the investigation site may encompass a specific SWMU or a larger area of concern (AOC) that includes several SWMUs. The RFI results will effect one or more of these actions: (1) NFA is required, (2) CMS is necessary, (3) interim corrective measures are necessary, or (4) referral to another authority to address problems related to permitted releases.

- **CMS** - A CMS is an "engineering evaluation" designed to evaluate and recommend the optimal corrective measure(s) at each SWMU where contaminant levels exhibit unacceptable risks. Medium-specific cleanup levels protective of human health and ecological receptors are developed, and the boundaries or point(s) of compliance are set. At this project phase or before the CMI phase, RCRA provides the designation of an AOC in which remediation wastes may be moved and managed (according to the approved corrective measures) without triggering land disposal restriction regulations under 40 CFR Part 268. Note that a typical CMS is more focused than is usually done for CERCLA FSs. The remedy selected from all potential remedial alternatives, including the "NFA" alternative, should be based on four criteria:

  - Protection of human health and the environment.
  - Attainment of media cleanup standards.
  - Control of sources to eliminate harmful releases.
  - Compliance with RCRA's waste management and disposal requirements.

- **CMI** - A CMI includes the actual design, construction, operation, maintenance, and periodic evaluation of the selected corrective measures.

EPA can impose interim corrective measures on RCRA facilities under corrective action to protect human health and the environment. The interim corrective measures can be taken at any time during the corrective action process.

EPA is accelerating cleanups at RCRA corrective action sites by promoting the reduction of exposure and further releases of hazardous constituents until long-term remedies can be selected. These accelerated cleanup actions are known as "Stabilization Initiatives" (USEPA, 1992n) and are similar in concept and application to the Superfund Accelerated Cleanup Model (SACM) under CERCLA (USEPA, 1992g).

1.3.3 Functional Equivalency of the CERCLA and RCRA Processes. The RCRA and CERCLA programs use different terminology, but follow parallel procedures in responding to releases. In both programs, the first step after discovery of a site is an examination of available data to identify releases needing further investigation. This step is called PA/SI in the CERCLA process and RFA in the RCRA process. If imminent human health and/or environmental threats exist, a mitigating action is authorized, known as a removal action under CERCLA Section 106 or an interim measure under RCRA Section 7003 or 3005(c)(3). Both programs require an in-depth characterization of the nature, extent, and rate of contaminant releases, called an RI in the CERCLA process and an RFI in the RCRA process. This is followed by a formal evaluation and selection of potential remedies in the FS (CERCLA) or CMS (RCRA) project phase. The selected remedy is executed by a RD/RA under the CERCLA process or CMI under the RCRA process. A specific discussion of the functional equivalency of both programs is presented in the preamble discussion of the July 27, 1990 proposed rules for Corrective Action for SWMUs at Hazardous Waste Management Facilities. A diagram comparing the RCRA and CERCLA processes is presented in Figure 1-1.

1.3.4 Role of Risk Assessment in the HTRW Process. Risk assessment has been consistently used as a decision-making tool in one or more steps in the

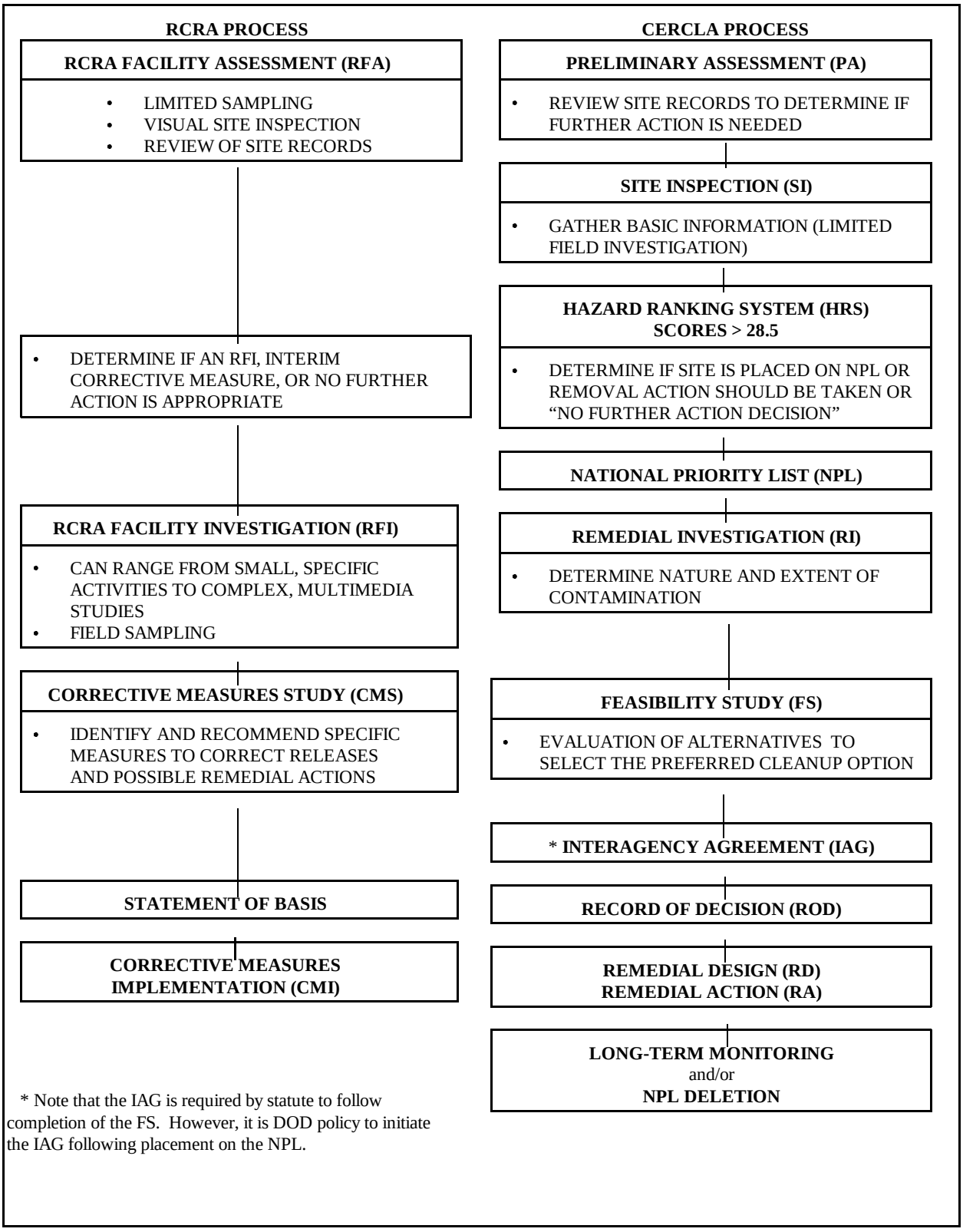

Figure 1-1. Comparison of RCRA and CERCLA processes.

CERCLA and RCRA corrective action processes. A risk screening analysis is used during the PA/SI to determine whether a site may be eliminated from further concern or requires further study, which may be focused on specific areas of the site. A BRA is conducted in the RI. Section 105 of CERCLA/SARA charges the On-Scene Coordinator or Remedial Project Manager (RPM) with the responsibilities of identifying potential impacts on public health, welfare, and the environment, and setting priorities for this protection which is delegated to DOD under Section 115 and EO 12580 for DOD facilities. RCRA Section 3019 requires the facility owner/operator to submit an Exposure Information Report (EIR) which provides exposure and health assessment information for certain storage and land disposal waste management units. In the RFI, as required by permit conditions or enforcement actions under RCRA Sections 3008(h), 7003, and/or 3013, a Health and Environmental Assessment (HEA) is used to determine quantitatively if the site or any of its units has exceeded established health criteria. As indicated in the RFI guidance (USEPA, 1989f), a site-specific risk assessment will be performed prior to the CMS to assess potential risk to humans and to determine if no response action is appropriate. Under CERCLA Section 120, the BRA is one of the primary documents identified for submission to EPA for comment and review in the Federal Facility Agreement (FFA).

Risk assessment in reverse is used to develop risk-based Remediation Goals (RGs) under CERCLA or Target Cleanup Levels (TCLs) (CERCLA Section 121) or Alternate Concentration Limits (ACLs)[6] under RCRA (40 CFR 264.94 and 264.100). Risk-based RGs, TCLs, or ACLs should be developed after the BRA has been performed incorporating site-specific factors in the calculations. Preliminary Remediation Goals (PRGs), corrective action levels, or soil screening levels can be developed at any time in the site investigation process, to determine whether further action is appropriate and to help focus subsequent studies on significant pathways of exposure. The summary or conclusions of the RI BRA, development of RGs based on allowable exposure, and analysis of alternatives (based on risk and the other criteria) are part of the FS report (USEPA, 1988i).

To be protective of human health, interim corrective measures or remedial alternatives must also be evaluated based on their ability to reduce site risk and their potential impact to humans during and after remediation. This risk evaluation of remedial alternatives is part of the remedy or corrective measure selection process prior to RD/RA (CERCLA Section 121, NCP Section 300.430(e)(1)), and Proposed RCRA Corrective Action Rule, Section 264.525(b)(55 FR 30798, July 27, 1990 and 61 FR 19431, May 1, 1996).

Performing a risk assessment is an iterative process. Risk assessment information is continuously being collected during the HTRW site investigation process, leading to the characterization of risks and uncertainties qualitatively or quantitatively. Risk assessment information is used during various stages of the HTRW site decision process as described below:

1.3.4.1 PA/SI, RFA, or Other Preliminary Site Investigation Activities. In this phase of the site investigation process, risk assessment information is used to determine whether a site may be eliminated from further concern, to identify emergency situations which may require immediate response actions/interim corrective measures, to assess whether further site
investigations are required, to develop a data collection strategy, and to set site priority (e.g., to rank sites).

It is important that the limited information gathered in this phase support the risk screening analysis and the HRS scoring if further site investigations are required. Accurate site information should be made available to the ATSDR in an attempt to avoid having health consultations or an advisory issued for the site by ATSDR based on inaccurate site information.[7]

[6] ACLs are allowable for ground water contamination only and do not address contamination of other media. Cleanup levels for surface water, sediment and soil are determined utilizing risk assessment as is done in CERCLA.

[7] Under CERCLA Section 104(j)(6), ATSDR is required to conduct health assessment under this Section for sites where individuals may have been exposed to a hazardous substance for which the source is related to a CERCLA release. Health assessments are generally based on SI, RI, Superfund risk assessment (human health evaluation), and studies submitted to ATSDR. In addition, ATSDR may conduct an analytical investigation that evaluates the

1.3.4.2 RI, RFI, or Other Additional Site Investigation Activities. In this phase of the site investigation process, existing chemical data and other exposure information are generally available. Data collected in this phase should comprise those media and pathways identified in the preliminary screening, including background data. If the data are useable and appropriate for the potential exposure pathways considered to be complete, baseline risks can be estimated. The results of the risk assessment will be used in the FS to determine the degree of response action required. RAs should be initiated to address the risks associated with an operable unit (OU), a SWMU, an area of contamination (AOC), an area of interest/concern, or an exposure area or unit.

An OU, as defined in the NCP, "is a discrete action that comprises an incremental step toward comprehensively addressing site problems." OUs provide a procedural basis for phasing multiple control measures that make up an RA, which may be used as a construction management tool during installation of complex RA, and which can provide manageable geographic areas for study. Areas of a site which are concerned with a specific receptor group may be used as the basis of OU designation which allows for effective evaluation of exposure pathways, simplifying the risk assessment of the site into manageable components. DOD facilities are much larger than traditional Superfund sites, and designation of OUs is an important part of designing the risk assessment to effectively define RA requirements.

To avoid triggering RCRA land disposal restrictions or minimum technology requirements, OUs may be combined to form an AOC for the purpose of implementing response action. A similar concept has been applied for combining SWMUs. It should be noted that the BRA completed in the RI serves to identify the need for response action and the relative degree of response required based on protection of human health and the environment.

1.3.4.3 FS, RD/RA, CMS/CMI, or Other RD and Implementation Activities. During the feasibility, treatability, or other remedial measure study phase, an evaluation of short-term and long-term risks associated with remedial alternatives is required under CERCLA Section 121, as is the development of cleanup levels.

Risk-based RGs/TCLs/ACLs can be derived based on EPA-established procedures (e.g., RAGS Parts A and B).[8] Specifically, risk assessment will be used to select a remedy by comparing among the alternatives the potential human/environmental impact during remediation (short-term and long-term) and the residual risks after remediation. This comparative analysis can be performed qualitatively for the ability of the alternatives to achieve the RGs, TCLs, ACLs (along with other criteria such as cost and long-term effectiveness). A more effective approach for many sites will be to perform quantitative evaluation of the risks associated with each remedial alternative or corrective measure, based on the alternative's long-term and short-term impact on risk to receptors. All potential receptors during and after the RA periods should be considered.

As with environmental monitoring, risk assessment can play a key role in assessing the residual risks and to establish ACLs. It can be used as a measuring tool to gauge the success of the RAs or corrective measures. See RAGS, Part C (USEPA, 1991e), *Alternate Concentration Limit Guidance Part 1 - ACL Policy and Information Requirements* (EPA 1987b), and *Alternate Concentration Limit Guidance Based on 264.94(b) Criteria, Case Studies* (EPA 1988f).

1.3.4.4 Use of Risk Assessment in Special Studies. Risk assessment techniques are used in virtually all phases of CERCLA, RCRA, and other HTRW processes. Therefore, risk assessment should be planned for and conducted to provide input to discussions associated with each phase. There are also special studies in addition to

possible causal relationships between exposure to hazardous substances and disease outcome by testing a scientific hypothesis. Exchanges of information and reports with ATSDR will be coordinated through the U.S. Army Center for Health Promotion and Preventive Medicine (USACHPPM).

[8] This manual emphasizes the need for careful HTRW project planning for adequate data collection to support a site decision. Risk assessment is a powerful decision tool; yet, misapplication of risk assessment procedures and concepts and poor data quality and quantity could lead to inaccurate assessment of risk and may lead to incorrect or poor site decisions.

executable phases discussed previously, specifically, protectiveness or "How clean is clean?" The following are examples of risk assessment in special studies:

- ARAR waiver - EPA has indicated that a non-zero Maximum Contaminant Level Goal (MCLG) is an - ARAR in the remedy selection. MCLG does not take into account specific site conditions and exposure patterns or economic and technical feasibility of implementation. Even though the non-zero MCLG may be considered an ARAR, a risk assessment can be used to evaluate the appropriateness of the non-zero MCLG. If a site-specific alternative cleanup level is as protective, an ARAR waiver request may be submitted under CERCLA Section 121(d)(2). The same process may be used to waive state ARARs, some of which are based on aesthetics including sight and odor.[9]

- Emergency response - The effectiveness of a proposed removal action, particularly for non-time-critical response action, should be evaluated in terms of the ability of the response action to reduce exposure. A screening risk assessment can be conducted to evaluate the response actions for relatively straightforward sites, although a BRA may be more appropriate for complex sites and cost recovery actions. This is particularly critical since EPA and some states want to implement early actions and presumptive remedies for certain sites. USACE HTRW risk assessment staff and design districts should consider all options, based on effectiveness of the action, and other criteria in the risk reduction efforts.

- Compliance with state air programs - CERCLA and RCRA sites are potential sources of air emissions. These air emissions may be present before and/or during the response action (removal or remediation), or during the operation and maintenance of the response action. Of particular concern are volatile and semivolatile organic chemicals, particulate matter, heavy metals, and acids. Operations implemented during the cleanup process (i.e., RI, removal action, or construction of a selected remedy) may emit air pollutants. Examples of operations which may act as a source of air emissions include soil handling, air stripping, onsite incineration, and equipment used in solidification/stabilization processes. USACE risk assessors should consult with state air regulatory personnel to determine the exact risk assessment requirements for evaluating air pathway exposures within that state. If potential risks are determined following state guidelines, resulting requirements for air emission limitations or emission control technologies should be discussed with the appropriate USACE personnel on the RD team.

- Risk assessment will be useful to assess the impact of the response actions (new sources) and the baseline condition (an existing source), for attainment of the National Ambient Air Quality Standards and substantive requirements embodied in the State Implementation Plan (SIP). See *ARAR Fact Sheet - Compliance with the Clean Air Act and Associated Air Quality Requirements* (USEPA, 1992l).

1.4 CONCEPT OF RISK ASSESSMENT AND GOOD SCIENCE

Risk assessment can be qualitative or quantitative. It includes an integration of hazard (dose and response), exposure (intake), and characterization of the potential risks/hazards and uncertainties. The process relies on strong fundamental scientific principles; the management aspect relies on application of policy as well as professional judgment and experience. This view is reflected by the National Academy of Sciences (NAS) and EPA who recognized the inherent uncertainties in the risk assessment methodologies. The uncertainties are primarily caused by various unknowns in the risk estimate calculation, which, in many cases, requires making assumptions relating to predictive modeling or inferences of certain scientific principles (Federal Focus

[9] EPA has compiled thresholds for odor for chemicals based on an extensive literature search. The updated odor thresholds should be consulted to evaluate if the ARAR (if based on odor) is reasonable. See *Reference Guide to Odor Thresholds for Hazardous Air Pollutants Listed in the Clean Air Act Amendments of 1990*, (USEPA, 1992f).

Inc., 1991).[10] This paragraph highlights the principles, instructions, or recommendations of assessing the impact on human health from chemicals in the environmental media at HTRW sites.

1.4.1 Basic Concepts. The fundamental principles of good science and quality entail the thorough understanding of: (a) site chemical data; (b) an understanding of site-related and background risks; (c) physical, chemical, and toxicity information associated with site chemicals; (d) fate and transport of site chemicals; (e) intake and extent of absorption; (f) the dose-response relationship of site chemicals; (g) uncertainties and limitations of the derived risk estimate; and (h) the best approach to characterize risk objectively.

The application of good science or definition of quality in the risk assessment reduces or defines uncertainties in a risk assessment. This application results in an unbiased risk characterization which allows risk managers to make informed site decisions. If the risk assessment uncertainties are well documented, and the results presented in a manner which can be easily understood by decision-makers, then this element of decision-making has more meaning relative to the other elements of risk management.

1.4.2 Risk Assessment as Decision Criteria in the HTRW Program. The role of a risk assessment in the site decision-making process at CERCLA and RCRA Corrective Action sites has been well defined by EPA either through rule-making or program directive/guidance. Therefore, risk assessments have been used as decision criteria in the USACE's HTRW program involving CERCLA and RCRA sites. For BRAC, FUDS, or other HTRW work which may not be on the NPL, risk assessments should be similarly applied. Activities at these sites require the evaluation of potential health and environmental risks in order to return the property to conditions appropriate for the current and planned future land uses. Therefore, a site-specific BRA is an important decision tool to USACE customers. If cleanup is needed, the extent or level of cleanup required will be based on results of the BRA, in addition to ARARs or other non-risk factors. Therefore, risk assessment is used as a decision tool at all HTRW response action sites.

1.5 POLICY CONSIDERATIONS AND RISK MANAGEMENT

This section presents a general discussion of the influence of policy considerations in risk assessment and risk management. Because of the implications of policy considerations on the site decision process, the risk assessors and risk managers are encouraged to identify the policies early in the decision process.

Unlike regulations which are enforceable, policies or published guidelines are administrative procedures or requirements concerning certain environmental regulations. DOD has issued directives to components (Army, Navy, Air Force, and Defense Logistic Agency),

[10] There can be significant uncertainties in the input parameters used in the risk assessment model, assuming that the model is the best scientific representation which can be used to predict potential health consequences from the exposure to chemicals in the environment. Since these models are used to support site decisions and policy-making, quantitative examination of these uncertainties is important. Presentation of risk estimates under the average and reasonable maximum exposures (RME) is now required by EPA's Superfund office. Recently, there has been an increased use of Monte Carlo (MC) analysis to propagate uncertainties through repetitive risk assessment calculations. Two examples of the application of MC are: (1) to determine a more accurate estimate of "reasonable maximum" risk than the use of standard default (normally high end) values for exposure input factors which could magnify risks to the Theoretical Upper Bound Estimate region of the risk probability curve, and (2) to evaluate the trade-off between extent (and thus cost) of remediation and degree of confidence in achieving adequate protection of health. MC can be used to provide risk estimates based on simulations of only a few key parameters which could substantially impact risks. These parameters are normally identified by performing a sensitivity analysis which compares the relative impact on the risk estimates (ranges) associated with each input parameter's maximum and minimum values while keeping other parameter values unchanged. There are off-the-shelf computer software programs for MC analysis in risk assessment, e.g., Crystal Ball®, At-Risk®, and others.

reaffirming DOD's commitment to comply with specific environmental laws or EOs. The respective components have also issued directives or orders expressing the same procedures or requirements. USACE will follow such policies or directives issued by DOD or its components regarding compliance with Federal environmental laws in the execution of HTRW response action at DOD installations or facilities. Some states or regional environmental control boards have also issued environmental policies or guidance. In the unlikely event that a policy is scientifically incongruent with site situations, early identification and resolution are critical. HQUSACE or HTRW CX technical staff should be consulted in these instances. All major policies used in making site decisions should be identified in the ROD or site decision documents so that the USACE customers and other stakeholders can judge the merit of these policies in achieving protection of human health and the environment.

1.5.1 Relationship Between Policy Considerations and Risk. A risk assessment is the technical evaluation of the degree of hazard or risk associated with exposure to contamination of an environmental medium or media. Risk management is oriented toward deciding whether RAs are warranted in light of the results of a risk assessment. The NAS National Research Council (NRC) defines risk management as "the process of weighing policy alternatives and selecting the most appropriate regulatory action, integrating the results of risk assessment with engineering data and with social, economic and political concerns to reach a decision" (NRC, 1983). NAS has identified four key components in managing risk and resources: public participation, risk assessment, risk management, and public policy decision-makers (NRC, 1994).

In making risk management decisions, the risk manager considers the degree of risk, technical feasibility to address risk, costs and benefits, community acceptability, permanence of the proposed actions, and other similar factors which are subject to policy considerations or regulatory requirements. As such, risk management is an important part of the USACE HTRW site response process, as it combines results of the risk assessment, regulatory requirements, and applicable agency policies (e.g., applicable DOD policies for defense sites).

1.5.2 USACE Policy Considerations. In an effort to standardize risk assessment procedures within the USACE HTRW program, the following considerations should be consistently applied to all site-specific risk assessments. Although not designated as DA or USACE policy at this time, these issues are based on sound science and will assist in making risk management decisions. At the appropriate locations within the text (see paragraph references below), these policy considerations are presented in bold typeface within double outlined text boxes, including implementation directives, as required.

- The risk assessment shall be given, at a minimum, equal consideration with other factors in the risk management decision. See Paragraph 6.1.

- All risk assessments shall include a statistically robust, significant, and defensible set of background concentrations. See Paragraph 4.3.3.2.2.

- Future land uses for risk assessment purposes and for development of remedial action objectives (RAOs) shall be land uses that are reasonably expected to occur at the site or facility. See Paragraph 4.4.4.

- If the cumulative site risk calculated in the risk assessment does not exceed 1E-04 for reasonable exposure scenarios, ARARs are not exceeded, and ecological impacts are not significant, no RA should be required. See Paragraph 6.2.2.

- The exposure assessment of a risk assessment shall utilize site-specific frequencies and durations whenever possible. A minimum of two risk estimates should be presented for each land use scenario, the RME and the central tendency (CT). See Paragraphs 4.4.5.1.3 and 4.4.5.1.6.

- Use of the EPA's Integrated Exposure Uptake and Biokinetic (IEUBK) model for lead exposures should be limited to residential, childhood exposures only. Where non-residential exposures are expected, an adult lead intake model should be used. See Paragraph 4.5.7.1.2.

- RGs must be developed and applied in the context of exposure area and exposure point concentrations. It

is unnecessary to remediate all media to or below the RG. See Paragraph 5.2

1.5.3 EPA Headquarters, Regional and State Policies. To successfully complete a risk assessment for use in making site decisions, HTRW project managers (PMs) and risk assessors generally work with Federal, regional, and state regulatory agencies to identify their specific policies or procedural requirements. HTRW risk assessors should identify and assist, where appropriate, in negotiations with the agencies on policies, procedures, and assumptions which are questionable.

All HTRW response actions should be in compliance with the Regulatory Policy Guideline issued under EO 12498 (1985), which states, "Regulations that seek to reduce health or safety risks should be based upon scientific risk assessment procedures, and should address risks that are real and significant rather than hypothetical or remote." Whenever possible, USACE's HTRW position should be supported by scientific principles, site data, or literature values. USACE recognizes that at times, agencies have to set policies in the absence of scientific consensus; however, USACE, through the HTRW program, is responsible for applying such policies properly and objectively based on site-specific considerations.

1.5.4 Risk-Based Management Decisions for Site Actions. Risk managers select the most appropriate remedy by considering "trade-offs" among different remedial alternatives and evaluating the ability of the alternatives to accomplish the overall project objectives. To improve the quality of risk-based management site decisions, HTRW risk assessors should identify key information that can affect that decision-making. This information should include policy considerations, assumptions concerning the margins of safety, and the use of other relevant data not associated with the site in the risk assessment. The sources of such policies and data, as well as the qualifications of persons/organizations recommending the policies or use of data, should be clearly identified. HTRW risk assessors can further help risk managers by providing an explanation of uncertainties in the risk assessment. When science deviates from policies or assumptions inherent in the risk assessment, it is the responsibility of HTRW risk assessors to clearly identify these instances as potential uncertainties as well.

1.6 REGULATORY DIRECTIVES AND GUIDANCE

This section highlights major EOs, Federal statutes/regulations under which the HTRW programs operate, and EPA risk assessment guidelines which provide the basis for development of this handbook. Irrespective of the procedures or mechanics for conducting risk assessments according to regulatory guidelines, all risk assessments performed under the HTRW response action must be based on "good science" and reasonable and unbiased scientific judgment. Although this section lists only major applicable EOs and directives, others may be accessed through the appropriate agencies and databases on the Internet.

1.6.1 EOs and Federal Statutes/Regulations.

EO 12088 (1978), *Federal Compliance with Pollution Control Standards*, established the mechanism by which the Executive Branch assures that its facilities (in various departments) meet their compliance responsibilities by complying with substantive and procedural requirements of Federal environmental statutes. These statutes include: Endangered Species Act (ESA); the Clean Air Act (CAA); the Federal Water Pollution Control Act (Clean Water Act [CWA]); the Solid Waste Disposal Act (as amended by RCRA); the Noise Control Act; the Marine Protection, Research and Sanctuaries Act (Ocean Dumping Act); the Safe Drinking Water Act (SDWA); the Toxic Substances Control Act; the Federal Insecticide, Fungicide, and Rodenticide Act; and the National Historic Preservation Act.

EO 12498 (1985), *Government Management*, incorporates by reference the regulatory principles contained in a Task Force report regarding future significant regulatory actions. Two principles of interest are:

- Regulations that seek to reduce health or safety risks should be based upon scientific risk-assessment procedures, and should address risks that are real and significant, rather than hypothetical or remote; and

- To be useful in determining overall benefits and costs, risk assessments must be scientifically objective and include all relevant information. In particular, risk assessment must be unbiased best estimates, not hypothetical "worst cases" or "best cases." In addition, the distribution of probabilities for various possible results should be presented separately, so as to allow for an explicit "margin of safety" in final decisions.

EO 12580 (1987), *Superfund Implementation*, requires all Federal agencies to comply with CERCLA/SARA and NCP in the same manner as the private sector. This Order delegated to the Secretary of Defense the response authority of DOD, which includes removal/RAs, site investigation and risk assessment, remedy selection, performance of PAs, and assuming natural resource trustee's responsibilities for current and former DOD facilities, and others. The Office of the Deputy Under Secretary of Defense for Environment Security (ODUSD[ES]) is responsible for carrying out the Secretary's responsibilities and administering the DERP in compliance with this Order.

EO 12777 (1991), *Implementation of Section 311 of the Federal Water Pollution Control Act of October 18, 1972 and the Oil Pollution Act of 1990*, delegates to the EPA and Coast Guard various responsibilities assigned to the President under CWA Section 311 and the Oil Pollution Act of 1990.

Other relevant EOs include: EO 11990 (1977), *Protection of Wetlands* and EO 11988 (1977), *Floodplain Management*.

RCRA 1976, as amended by the HSWA of 1984, has the objectives to protect human health and the environment, reduce waste and conserve energy/natural resources, and to reduce or eliminate generation of hazardous waste:

- Subtitle D - solid waste (encourages states to develop and implement solid waste management plans to provide capacity).

- Subtitle C - hazardous waste program (identifies hazardous wastes and regulates their generation, transportation, and TSD; authorizes states to implement the hazardous waste program in lieu of EPA; requires permits for TSD facilities).

- Subpart S - Proposed Corrective Action Rule (provides procedures for implementing RCRA corrective action) (55 FR 30797, July 27, 1990 and 61 FR 19431, May 1, 1996).

- Subtitle I - UST (regulates petroleum products and hazardous substances stored in underground tanks; requires compliance with performance standards for new tanks; and requires leak detection, prevention, closure, financial responsibility, and corrective action).

CERCLA of 1980, as amended by the SARA of 1986 (42 U.S.C. 9601 et seq.) provides broad Federal authority to respond directly to releases or threatened releases of hazardous substances that may endanger public health or the environment. SARA defines the process Federal agencies must follow in undertaking RA, including a requirement that EPA make the final selection of remedy if there is a disagreement between the Federal agency and EPA.

The NCP (55 FR 8660, 9 March 1990) provides procedures and standards for how EPA, other Federal agencies, states, and private parties respond under CERCLA to releases of hazardous substances. The NCP authorizes the U.S. Department of Interior and other agencies, states, or entities to be the "trustees" of natural resources to recover compensatory damages for "injury to, destruction of, or loss of natural resources resulting from a discharge of oil into navigable waters or a release of a hazardous substance."

Federal Facility Compliance Act (PL-102386, October 21, 1992) directs Federal agencies to comply with Federal and state environmental laws, and provides authority to EPA to impose penalties on other Federal agencies for noncompliance. Among others, it amended Section 6001 of RCRA to waive immunity of the United States (Federal department, agency, or instrumentality of the United States) to administrative orders and civil penalties or fines associated with Federal, state, interstate, and local solid and hazardous waste management requirements. Section 3004 of RCRA was also amended to require EPA, in consultation with DOD, to identify and regulate waste military munitions which are hazardous.

1.6.2 DOD Directives.

DOD Directive 5100.50 (DOD, 1973), *Protection and Enhancement of Environmental Quality*, establishes procedures and assigns responsibilities for use of DOD resources in the protection and enhancement of environmental quality and establishes the DOD Committee on Environmental Quality.

DOD Directive 5030.41 (DOD, 1977a), *Oil and Hazardous Substances Pollution Prevention and Contingency Program*, sets forth DOD policy in support of the NCP.

DOD Directive 4120.14 (DOD, 1977b), *Environmental Pollution, Prevention, Control, and Abatement*, implements within DOD new policies provided by EO 12088 and Office of Management and Budget (OMB) Circular A-106, and establishes policies for developing and submitting plans for improvements needed to abate air and water pollution emanating from DOD facilities.

DOD Directive 6230.1 (DOD, 1978), *Safe Drinking Water*, sets forth DOD policy for provision of safe drinking water and compliance with the SDWA.

DOD Directive 6050.1 (DOD, 1979), *Environmental Effects in the United States of DOD Actions*, implements the Council of Environmental Quality (CEQ) regulations and provides policies and procedures to take into account environmental considerations in DOD actions.

1.6.3 EPA Headquarters and Regional Guidance.

CERCLA

Guidance documents (Office of Solid Waste and Emergency Response [OSWER] Directives) for conducting various phases of a CERCLA response action have been developed or are being finalized by EPA headquarters. Key CERCLA guidance documents are identified below (also see Appendix A):

- *Guidance for Performing Preliminary Assessments Under CERCLA* (USEPA, 1991c). This document provides the PA objectives, data requirements, the procedural steps to complete the PA, and develops a site score using PA score sheets. It also provides guidelines for reviewing the site evaluation and score, including identification of sites for emergency response actions.

- *Guidance for Performing Site Inspections Under CERCLA* (USEPA, 1992m). This document provides the approaches, data acquisition planning needs, sampling strategies, data evaluations using the SI worksheets, and reporting requirements for the CERCLA SI. The document describes the approach of using a focused SI to test the PA hypotheses, resulting in one of three recommendations: (1) site evaluation accomplished, (2) expanded SI to collect additional data, or (3) preparation of an HRS package for placement of the site on the NPL if the HRS scoring data requirements have been met.

- *Hazard Ranking System Guidance* (USEPA, 1992a) provides guidance to individuals responsible for preparing HRS packages for sites for of sites on the NPL.

- *Guidance for Conducting Remedial Investigations and Feasibility Studies Under CERCLA* (USEPA, 1988i). This guidance describes the CERCLA RI/FS process to characterize the nature and extent of contamination or risks posed by a site and to evaluate whether RA is needed. It describes the site characterization techniques, the role of a BRA, feasibility studies, and development of screening and detailed analyses of remedial alternatives.

- *Guidance for Data Useability in Risk Assessment (Part A)* (USEPA, 1992h) and *(Part B)* (USEPA, 1992k). These guidance documents provide approaches and recommendations for defining, planning, and assessing analytical data for the BRA.
- RAGS was published in two volumes: *Volume I, Human Health Evaluation Manual* (USEPA, 1989j), and *Volume II, Environmental Evaluation Manual* (USEPA, 1989b). A compendium method handbook (USEPA, 1989c) was published concurrently with the Environmental Evaluation Manual. As the science of ecological risk assessment has developed, additional guidance has been published to superceed the Environmental Evaluation Manual. *Ecological Risk Assessment Guidance for Superfund: Process for Designing and Conducting Ecological Risk Assessments* was published as Interim Final on June

5, 1997 (USEPA, 1997b) and the *Guidelines for Ecological Risk Assessment*, published as Final in April 1998 (USEPA, 1998b). Volume I has four parts:

- Part A (USEPA, 1989j) provides a detailed discussion on how a BRA should be conducted. It presents key components of a risk assessment: data collection and evaluation, exposure assessment, toxicity assessment, risk characterization, and uncertainty discussion.

- Part B (USEPA, 1991d) presents the methodologies and algorithms to calculate risk-based PRGs for individual chemicals in the soil, ground water, and air media, and the transformation of PRGs to RGs or cleanup levels using site-specific information. It stresses that risk-based cleanup levels are to be considered along with ARARs, remediation technology, and analytical detection limits (DLs), etc., in the risk management and remedy selection processes.

- Part C (USEPA, 1991e) presents the approach and risk information used to evaluate remedial alternatives during the FS. The evaluation (either qualitative or quantitative) compares risk-based benefits of alternatives, investigates potential risks to the nearby communities (short-term and long-term/residual) and remediation workers (short-term), determines the need for engineering controls to mitigate potential risks, and assesses the need for a 5-year review indicated in the NCP. The guidance describes selected remediation technologies and provides references for quantifying the potential releases from conducting such remedial activities.

- Part D (USEPA, 1998a). The EPA was directed to establish national criteria to plan, report, and review Superfund risk assessments. The RAGS Part D approach includes three basic elements: (1) Use of the Standard Tools, (2) Continuous Involvement of EPA Risk Assessor, and (3) Electronic Data transfer to the National Superfund Database. Additionally, EPA is developing standard approaches for lead risks, radionuclide risks, probabilistic analyses, and ecological evaluation that will be issued as revisions to RAGS Part D.

  The approach contained in RAGS Part D is intended for all CERCLA risk assessments. Its use is also encouraged in ongoing risk assessments to the extent it can efficiently be incorporated into the risk assessment process. Part D is also recommended for non-NPL sites, BRAC sites and RCRA sites when appropriate. Chapter 1 of RAGS Part D provides more detailed guidelines regarding its applicability as a function of site lead and site type. Each EPA region will determine the site-specific applicability, but USACE risk assessors should consider its use on all projects.

- EPA regional guidance documents for risk assessment. Various EPA regions have also supplemented the national EPA risk assessment guidance with their own policies and procedures for use in conducting a BRA. These guidance documents, in the form of memoranda, directives, or stand-alone documents, address a wide range of issues. These issues include adjustment of critical toxicity factors, data presentation and qualifications, use of MC simulations in risk characterization, selection of ground water data to estimate the reasonable maximum exposure point concentration, toxicity equivalency factors for polycyclic aromatic hydrocarbons (PAHs), soil/dermal adherence factors, midrange (CT) values for exposure parameters, selection of COPCs, screening risk assessment methods, and others.

RCRA

Limited guidance has been developed for conducting various phases of a RCRA facility response action to address current or past releases. The key RCRA guidance documents that are available are identified below:

- *RCRA Facility Assessment Guidance* (USEPA, 1986) provides guidance for conducting facility assessments to reflect developments of the RCRA corrective action programs. Also clarifies the definition of SWMU.

- *RCRA Corrective Action Interim Measures Guidance* (USEPA, 1988g) assists EPA regions and states in performing corrective action interim measures to mitigate or remove an exposure threat presented by releases.

- *RCRA Corrective Action Plan* (USEPA, 1988a) provides technical framework for developing corrective action orders and corrective action permit requirements.

- *RCRA Facility Investigation (RFI) Guidance* (USEPA, 1989f) provides general guidelines for performing health and environmental evaluations are described in this four-volume guidance manual. With regard to performing environmental risk assessments, this guidance is substantively equivalent to RAGS and references the CERCLA methodology.

1.6.4 State Requirements/Guidance. HTRW risk assessors and PMs need to be aware of any risk assessment procedures, data needs, or programs specific to the state in which their site is located. Almost all states have been authorized for RCRA permitting; some have corrective action authorities. Many states have statutes and regulations that address uncontrolled hazardous waste sites and SWMUs associated with regulated RCRA facilities. Also, many states have primacy in the water pollution control program (under the CWA) and have either adopted EPA criteria or developed their own water quality standards. Many states have adopted the use of risk assessment for corrective action to demonstrate "how clean is clean," to develop site-specific cleanup goals, to evaluate facilities burning hazardous waste, or for other uses.

Some states (e.g., California and New York) have risk assessment policies which may be interpreted as substantially similar to RAGS. Other states (e.g., Connecticut and Kentucky) have adopted RAGS as a matter of policy. Some states (e.g., Ohio and Massachusetts) have developed formal risk assessment guidelines, ranging from calculation of exposure point or background concentrations to the adjustment of critical toxicity values. Ohio and Tennessee recommend a health risk assessment be performed for RCRA corrective action and closure to demonstrate “how clean is clean.” Some states (e.g., Kentucky, Michigan, New York, Oregon, and Texas) allow the use of risk assessment to derive ACLs and medium-specific action levels or risk reduction standards. A few states (e.g., Connecticut and Illinois) have simple procedures in place (such as 20 times the maximum concentration of contaminants for the toxicity characteristics or use of equilibrium partitioning) to derive preliminary soil/sediment cleanup levels. In general, risk assessment or analysis procedures vary from state to state, and sometimes within different departments or among state agencies.

1.6.5 Others.

U.S. Army (USA)

AR 200-1 (USA) designates USACHPPM (formerly the U.S. Army Environmental Hygiene Agency) to oversee and recommend approval or disapproval on behalf of the U.S. Army Office of The Surgeon General on all risk assessments prepared by executing agencies for Army IRP sites, Army BRAC sites, and FUDS. USACHPPM is the DOD Lead Agent and Army liaison office for the ATSDR program. USACHPPM works with the military components and ATSDR to prevent exposures at hazardous waste sites and to prevent any potential adverse health effects associated with such exposures. USACHPPM executes the Memorandum of Understanding between DOD and ATSDR, and identifies requirements and negotiates and Annual Plan of Work with ATSDR.

U.S. Air Force (USAF)

The Office of the Air Force Surgeon General's Biomedical Engineering Service (BES) is responsible for providing technical support for all Air Force DERP CERCLA activities. The Air Force *Installation Restoration Program Management Guidance* (USAF, 1989) and Fiscal Year (FY) 93/94/95 *DERA Eligibility and Programming Guidance* (USAF, 1992) provide guidance in this area. Work relating to hazardous waste management activities under RCRA is performed by the BES in accordance with Air Force Regulation 19-7 and *USAF Hazardous Waste Management Policy* (USAF, 1991). Currently, the environmental service centers for USAF, such as the Air Force Center for Environmental Excellence, USACE, or the risk assessors at respective

Major Air Force Commands review risk assessments in coordination with the Air Force Surgeon General.

U.S. Navy and Marine Corps

The Chief of Naval Operations directive OPNAVINST 5090.1B (DON, 1994), Department of the Navy (DON), assigns command responsibilities and provides Navy policy to comply with environmental laws and regulations. *The Navy and Marine Corps Installation Restoration (IR) Program Manual* (DON, 1992) describes the Navy organization/responsibilities in support of IRP, priority for funding, research, training, and reporting requirements including preparation of Pollution Control Report to satisfy the OMB Circular A-106 reports to EPA. The Naval Environmental Health Center, under the direction of the Bureau of Medicine and Surgery, provides a wide range of medical consultative services to the Naval Facilities Engineering Command community in support of the IRP, the BRAC Program and other related environmental projects. Consultative support services include but are not limited to review of IRP and BRAC program documents (e.g., work plans, sampling and analysis plans (SAPs), quality assurance/quality control (QA/QC) plans; RI/FSs, risk assessments, health and safety plans) from a risk assessment and public health perspective; conducting risk evaluations or quantitative risk assessments; training in risk assessment, public health assessment, health and safety plans, and risk communication; sponsoring the 3-day tri-service Environmental Risk Communication and Public Dialogue Workshop; negotiating with regulators regarding the use of realistic exposure assumptions; assisting in developing community relations plans; assisting in establishing Restoration Advisory Boards; assisting in preparing correspondence from a risk communication perspective; preparing posters for public exhibits and public meetings; acting as the DON liaison for ATSDR issues.

USEPA

The USEPA has published a number of enforcement policies and procedures for Federal facilities, e.g., *Federal Facilities Compliance Strategy* (USEPA, 1988j), *Enforcement Actions Under RCRA and CERCLA at Federal Facilities* (USEPA, 1988b), *Evaluation Process for Achieving Federal Facility Compliance* (USEPA, 1988c), *Federal Facilities Negotiations Policy* (USEPA, 1989h), and *Federal Facilities Hazardous Waste Compliance Manual* (USEPA, 1990a). All Federal agencies are required to comply with hazards waste regulations and the NCP in the same manner as the private sector.

U.S. Department of Energy (DOE)

The DOE has issued a number of orders (5400 series and others) addressing a variety of environmental statutes and requiring all facilities to comply with the applicable environmental laws and regulations. For example, DOE Order 5400.2A (DOE, 1993) sets forth policy, direction, and procedures for coordinating environmental compliance issues and DOE Order 5400.4 (DOE, 1989) addresses "CERCLA Requirements." The Office of Environmental Guidance of DOE has a plan in place to develop a comprehensive guidance and training program for its field facility staff and Environmental Restoration Project Managers. In the area of risk assessment, the DOE guidance or information briefs include: *Integrated Risk Information System* (DOE, 1991), *CERCLA Baseline Risk Assessment* (DOE, 1992a), and *Use of Institutional Control in CERCLA Baseline Risk Assessment* (DOE, 1992b).

1.7 FEDERAL FACILITY AGREEMENT

Although there may be subtle differences between an FFA and an IAG, these terms are used interchangeably under CERCLA Section 120 which addresses both NPL and non-NPL sites. This section focuses on the need for early planning and negotiation of an FFA among the USACE customer (a Federal agency), EPA, and the state agency (as appropriate). To accomplish this objective, the HTRW project team member (i.e., the risk assessor) and others should work cooperatively to develop statements/languages or addenda to the FFA early in the HTRW project cycle to define a flexible framework or process for RMDM and to facilitate site closeout protective of human health and the environment.

EO 12580 delegates DOD to conduct response action under Section 104 of CERCLA (as amended by SARA) to address releases on DOD facilities or originating from the facilities. The order requires that the response action be conducted in accordance with Section 120 of CERCLA. According to CERCLA Section 120(e)(1), DOD is directed to enter into an IAG with EPA for RA

within 180 days of EPA's review of the RI/FS. In the *Federal Facilities Hazardous Waste Compliance Manual* (USEPA, 1990a), EPA states, "At a minimum, the IAG must include a review of cleanup alternatives considered and the remedy selected, a schedule for cleanup accomplishment, and arrangements for operation and maintenance."

To address non-compliance issues at a Federal facility (e.g., a DOD installation), EPA may issue a complaint known as Notice of Noncompliance (NON). After such an issuance, EPA and the Federal facility enter into negotiation for a Federal Facility Compliance Agreement which resolves compliance violations and stipulates agreed-upon remedy, compliance schedule, and reporting and record keeping requirements. The target date for concluding such an agreement is within 120 days from the date of NON issuance (USEPA, 1990a). Since RCRA corrective actions are generally required at the time of RCRA Part B permitting or permit renewal, the Federal facility may be issued a RCRA Section 3008(h) corrective action order rather than a NON.

"Executive branch disputes of a legal nature are properly resolved by the President or his or her delegate..." (USEPA, 1990a). In view of the above, and for the purpose of this handbook, the risk assessor should provide assistance to the USACE's PM, risk manager, and the USACE customer so that an FFA or IAG can be successfully negotiated to provide a framework for RMDM and to initiate actions to protect human health and the environment where these actions are needed. The risk assessor and the HTRW project team may consider the following areas for assistance to be provided to the USACE customer concerning the FFA negotiation; these areas have been identified in the DOD-EPA Model IAG Language (USEPA, 1989h):

1.7.1 Basis for Interim Remedial Action (IRA) Alternatives. For purposes of this guidance, IRA may be interpreted as interim corrective measure under RCRA or interim removal action under CERCLA. One purpose of the FFA is to identify IRA alternatives which are appropriate at the site prior to the implementation of final RA(s). To identify such alternatives, the exposure area, the exposure pathways which contribute to the principal threat at the site, and the receptors/resources must also be identified. For the purpose of the FFA, a statement may be entered which indicates the basis for identifying IRA alternatives. This statement should address the following:

- The approach for conducting a screening risk analysis of the Exposure Units (EUs) (USEPA, 1991a), SWMUs, or the AOCs.
- The evaluation method for the risk assessment/analysis results (qualitative or quantitative).
- RMDM considerations (see Chapter 6) for identifying and/or selecting the IRA alternatives.

1.7.2 Requirements for RI/RFI and FS/CMS. Another purpose of the FFA is to provide a framework for investigating, assessing the impact, and evaluating remedial options to protect public health and the environment. Such a framework, consistent with the NCP and the RI/FS guidance (USEPA, 1988i), may be modified and formally incorporated in the FFA to meet the site-specific and project requirements. Statements or languages or addenda to the FFA may be prepared by the risk assessor and the project team to serve as a basis for determining the extent of data collection, data evaluation, assessment of baseline risk, and evaluation of remedial alternatives. The HTRW TPP process (USACE, 1998) and associated DQOs should be identified as the framework for determining data needs, data use, and quality. The point of departure for NFA and/or monitoring only based on acceptable carcinogenic risk or hazard should be identified in the FFA (USEPA, 1991a). The statement should indicate the need for evaluating uncertainties in risk assessment by the use of multiple descriptors (i.e., RME, CT, population, and individual risks). One important statement that should also be considered for complex sites is the need for a probabilistic risk assessment to identify the confidence level of unacceptable risk or hazard, when the point estimate of risk derived by the deterministic approach (e.g., RAGS Part A, USEPA, 1989j) has marginally exceeded the acceptable risk or hazard levels. These probabilistic risks (cumulative function distribution) should be identified as an input into the RMDM for these site actions.

1.7.3 Expedited Cleanup Process. Both DOD and EPA are in agreement that early action or accelerated cleanup may be needed to stabilize the site and to

facilitate implementation of the final remedies. However, the basis for such action is not well defined, except that the actions are intended to control contaminant migration, to reduce exposure, and to accelerate response. In addition to time-critical and emergency response actions where safety and acute hazards are involved, the risk assessor and the project team can provide valuable input to the USACE customer and risk manager for such expedited actions. This can be rather quickly accomplished by comparing the measured media concentrations with available human health and ecological risk-based protective criteria. This may be useful for relatively straight-forward sites, such as drum removal, product removal, and containment. For response actions at a complex site, a BRA may be more appropriate, however, and expedited cleanup would not be done. All decision criteria for eliciting response actions to protect environmental components should be well thought out, reasonable, and consistent with current EPA guidance.

1.7.4 Units Excluded from the Agreement. RCRA and CERCLA integration issues should be addressed in the FFA in unambiguous terms. This is particularly true for sites of which the state agency is also an interested party or natural resource trustee in the agreement. Some state agencies have their own risk assessment policies and guidance, and RMDM criteria which may vary substantially from those of EPA (EPA's procedures under RCRA and CERCLA are judged to be substantially equivalent at this time). The risk assessor should review state policies, guidance, and requirements, to identify any critical risk assessment/risk management issues for the PM and the customer for resolution. These issues should be addressed and resolved in the FFA negotiations. If not successful, separate FFAs may be needed to address RCRA and CERCLA units within the facility. The USACE and customer's legal counsels should be contacted for briefing on these issues early in the process.